K083753

510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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JUN 19 2009

Name of Device

Arm Blood Pressure Monitor Smartlogic Model KP-7500 and Fuzzylogic Model KP-7500D

Name/Address of Sponsor

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: + 886 2 22991378
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Contact Person: Jason Cheng

Common or Usual Name

Arm Blood Pressure Monitor

Classification Name

Class II § 870.1130; System, Measurement, Blood Pressure, Non-Invasive

Predicate Device

I. K-jump Health Co., Ltd.'s Wristwatch BPM Blood Pressure Monitor Model KP-6210.
II. K-jump Health Co., Ltd.'s Arm BPM Blood Pressure Monitor Model KP-6821 and KP-6822.
III. MicroLife's Upper Arm Blood Pressure Monitor Model BP-3BT0-AP.

Intended Use/Indications for Use

The device is intended to measure the systolic and diastolic blood pressure and pulse rate (heart rate) by using an inflating cuff. The device is indicated for use with adults.

The device displays irregular pulse detection (IPD) icon on LCD screen when irregular pulse is detected during blood pressure measurement.

Technological Characteristics

The device is an electronic blood pressure monitor. The device consists of an inflating cuff, a LCD display, a bellows sensor, an internal air pump, a leakage valve, an exhaust valve, a battery power resource, and keys for operation.

Performance Data

The Arm Blood Pressure Monitor Model KP-7500 and KP-7500D complies with the following FDA-recognized consensus standards, to the extent that these standards are applicable to this device:

- AAMI/ANSI SP10 (2002 / A1:2003);
- IEC 60601-1 (1988); and
- IEC 60601-1-2 (2002).

The KP-7500 and KP-7500D also complies with the following additional

standards:

- EN61000-4-2 (1995); and
- EN61000-4-3 (2002).

In accordance with AAMI/ANSI SP10, a clinical trial also was performed to verify the accuracy of in-vivo measurement. The results demonstrate that the KP-7500 and KP-7500D accurately measures the patient's blood pressure and pulse rate.

Substantial Equivalence

The KP-7500 and KP-7500D have the same intended use and indications for use as K-Jump's Arm Blood Pressure Monitor Model KP-6210, K-Jump's Wristwatch Blood Pressure Monitor Model KP-6821 and MicroLife's Model BP-3BT0-AP.

The KP-7500 has the same technological characteristics as the KP-6210 except: (1) that the KP-7500 uses a bellows sensor; and (2) the KP-7500 is used on the upper arm rather than on the wrist.

The KP-7500D has the same technological characteristics as the KP-6821 except: (1) that the KP-7500D uses a bellows sensor; and (2) the KP-7500D displays blood pressure and heart rate on the same screen simultaneously rather than on subsequent, alternating screens.

Microlife's Model BP-3BT0-AP also uses a bellows sensor same as the KP-7500 and KP-7500D. Both devices include an irregular pulse detection function.

Thus, the minor differences between the KP-7500, KP-7500D and the predicate devices are not new technological characteristics for arm blood pressure monitors. The modification of the device's LCD display was made for user convenience. Therefore, these minor technological differences do not raise any new questions of safety or effectiveness. Accordingly, the KP-7500 and KP-7500D are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

K-jump Health Co., Ltd.
c/o Mr. Jason Cheng
Regulatory Affairs
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien 248
Taiwan

Re: K083753
Trade/Device Name: Arm Blood Pressure Monitor Smartlogic Model KP-7500 and Fuzzylogic Model KP-7500D
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Monitoring System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: June 12, 2009
Received: June 16, 2009

Dear Mr. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K083753

Device Name: Arm Blood Pressure Monitor Smartlogic Model KP-7500 and Fuzzylogic Model KP-7500D

Indication for Use:

The KP-7500 and KP-7500D are intended to measure the systolic and diastolic blood pressure and pulse rate (heart rate) by using an inflating cuff which is wrapped around the arm. It is indicated for use in adults.

The devices display irregular pulse detection (IPD) icon on LCD screen when irregular pulse is detected during blood pressure measurement.

Prescription Use _____ OR Over-The-Counter Use X

(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram Zuckerman

(Division Sign-Off) 6/9/09

Division of Cardiovascular Devices

510(k) Number K083753